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REMARKS

Claims 1-14, 18-22, and 24-27 are currently pending in the present application. No claim amendments are made in this response. New claims 28 and 29 are added. Applicant appreciates the courtesy of a telephone interview with the Examiner on October 20, 2005. The rejection of claims 18-22 and 24-27 under 35 U.S.C. §112, first paragraph, in the final Office Action mailed July 22, 2005, was overcome by the response filed September 21, 2005, as stated in the Advisory Action mailed September 30, 2005. Following the submission of a Supplemental Response on October 21, 2005, the Examiner mailed an Advisory Action on January 17, 2006, and maintained the obviousness rejection discussed below. The following comments and the concurrently filed Declaration of the inventor, Balaji Venkataraman, are filed to advance the prosecution of the patent application and overcome the remaining rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a).

This RCE is timely filed together with a petition for a three-month extension of time and the required fees.

Rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a)

In the final Office Action mailed July 22, 2005, The Examiner rejects claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 0 595 005 A1 (hereinafter the European Patent) in view of Shapira (U.S. Patent No. 5,993,866, hereinafter Shapira).

In the final Office Action mailed July 22, 2005, the Examiner asserts that Shapira discloses that magnesium is essential for the vitamin B6 function and cites column 6, lines 1-20 in this regard. Applicant previously addressed this rejection based on column 6, lines 1-20 of Shapira in the response filed September 21, 2005. Those remarks are included here for the sake of completeness in addressing the final Office Action.

Applicant respectfully asserts that Shapira incorrectly describes at column 6, lines 2-5 the content of Fonda et al., (1995, Arch. Biochem. Biophys. 320(2):345-52). The remainder of lines

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6-20 in Shapira discuss S adenosyl methionine (SAM) requirements for magnesium and are irrelevant. Fonda reports that magnesium affects erythrocytic pyridoxal phosphatases that catalyze hydrolysis of pyridoxal 5'-phosphate (PLP) (column 2, page 345 of Fonda (copy of Fonda filed September 21, 2005 as Exhibit A)). Erythrocyte pyridoxal phosphatases require magnesium for activity (column 2, 2nd paragraph page 345 of Fonda). Fonda does not disclose that magnesium is essential for vitamin B6 function, rather Fonda addresses the divalent cation requirements for the enzyme, erythrocyte pyridoxal phosphatase. For at least this reason, one of ordinary skill in the art would not interpret Fonda to state that magnesium is essential for vitamin B6 function, but is required as a cofactor for erythrocytic pyridoxal phosphatase. Further, one of ordinary skill in the art would not be motivated, reading the Fonda article (as misinterpreted by Shapira), which involves divalent cations as cofactors for pyridoxal phosphatase, to combine this information with the European patent and derive Applicant's claimed vitamin composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E, and its use for treating or preventing vascular disease. Applicant's invention is not concerned with divalent cation requirements for the enzyme, erythrocyte pyridoxal phosphatase. Vitamin B6 as pyridoxal, pyridoxamine or pyridoxine (page 6 of the specification) is a component of Applicant's vitamin composition, not the enzyme pyridoxal phosphatase. Applicant's also assert that one of ordinary skill in the art would not combine the cited references, as Shapira misquotes Fonda which is an enzyme kinetics manuscript, with the European patent involving pharmaceutical preparations. Applicant asserts that one of ordinary skill in the art would not combine references from these distinctive fields and that the combination is improper.

The Examiner also asserts that Shapira teaches that hyperhomocysteinemia relates to cardiovascular disease, and that this would provide motivation to one of ordinary skill in the art to use Applicant's composition for the treatment and prevention of vascular disease. Applicant's traverse and respectfully assert that Shapira, which misquoted the content of Fonda, does not provide motivation to use Applicant's claimed vitamin composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E. Nothing in Shapira, alone or in combination with the European patent, provides motivation to derive Applicant's claimed composition (reasons discussed above), or to use Applicant's claimed composition consisting of vitamin B12,

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vitamin B6, folic acid, magnesium, and vitamin E for the treatment and prevention of vascular disease.

In the Advisory Action of January 17, 2006, the Examiner maintains the obviousness rejection and cites column 1, lines 15-20 of Shapira. Applicant respectfully traverses this rejection. Applicant provides the following remarks and the concurrently filed Declaration of Balaji Venkataraman in order to address this rejection.

Shapira, at column 1, lines 15-20, and throughout the entire specification and claims is concerned with modification of food in order to reduce the homocysteinogenic potential of the food. Shapira discloses that this is accomplished by modifying the ratio of methionine in the food to nutritional factors involved in homocysteine metabolism. Shapira modifies a variety of foods and/or dairy products to reduce the ratio of methionine to B6 (mg/ml) below a starting ratio of methionine to B6 in the food. At column 1, lines 19-20, Shapira states that these cofactors are "mainly B6 and optionally with folic acid, B12, magnesium, cysteine." The entire disclosure of Shapira relates to modification of food to affect methionine to B6 ratios in the food, not preparation or use of a vitamin composition. Column 7, lines 48-61 of Shapira define the invention as consisting of a variety of foods and/or dairy products in which the ratio of methionine to B6 (mg/ml) is reduced below a starting methionine:B6 ratio. Shapira states at column 7, lines 53-61, that "The present invention thus consists in a variety of foods and/or dairy products in which the ratio methionine:Vit B6 (mg/mg) is reduced to below the starting (or base) methionine:vit B6 ratio...". Examples 1-30 in Shapira disclose such ratios in cottage cheese, milk, cream cheese, chocolate, yogurt, sour cream, fish, sausage, chicken drumsticks and other foods. Shapira adds folic acid, vitamin B6 and magnesium to food. Food contains numerous compounds, such as protein, carbohydrate, fat and methionine (see Shapira's Examples), and is different from Applicant's claimed vitamin composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E. No methionine, protein, carbohydrate, fat or other food compounds are present in Applicant's claimed vitamin composition. Shapira provides no suggestion or motivation to make vitamin compositions, as stated by the declarant. Shapira modifies food to reduce the homocysteinogenic potential of food, as stated by the declarant and also by Shapira.

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One of ordinary skill in the art would not be motivated, reading Shapira's disclosure of modification of methionine:B6 ratios in food, to combine this information with the European patent and derive Applicant's claimed vitamin composition consisting of vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E, and its use for treating or preventing vascular disease. There is no suggestion, motivation or teaching to combine these references. Applicant respectfully asserts that one of ordinary skill in the art of making vitamins would not be motivated to combine these references and that the combination is improper. The concurrently filed Declaration of the inventor attests to this and declares "...that Shapira, alone or in combination with European Patent No. 0 595 005, provides no suggestion or motivation to derive my claimed vitamin composition consisting of only the specified ingredients vitamin B12, vitamin B6, folic acid, magnesium, and vitamin E."

Applicant further asserts that Shapira is non-analogous art as Shapira is not in the field of Applicant's invention. The concurrently filed Declaration of the inventor attests to this assertion. The declarant states, as one of ordinary skill in the art of preparing vitamin compositions, that he does not peruse the literature describing modification of food, and therefore would not be aware of the Shapira reference. He further declares that the Shapira reference is in a non-analogous area compared to his invention, as claimed, directed to vitamin compositions and their use. Since Shapira is non-analogous art, Applicant asserts that its combination with the European patent is improper.

For at least the reasons presented above and in the previously filed response and in view of the concurrently filed Declaration, Applicant asserts that the cited art, alone or in combination, does not teach, suggest or provide motivation for one of ordinary skill in the art to derive the claimed vitamin composition, consisting of vitamin B12, vitamin B6, folic acid, magnesium and vitamin E, or its use in the recited method. Applicant respectfully asserts that the rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a) has been overcome and requests its withdrawal.

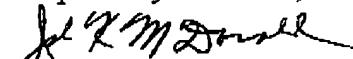
Applicant respectfully asserts that this response to the final Office Action is timely filed and that the rejections under 35 U.S.C. §103(a), delineated in the Office Action of July 22, 2005

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and in the Advisory Actions mailed September 30, 2005 and January 17, 2006, have been overcome. A Notice of Allowance is courteously requested. If any informalities remain which may be discussed, a conference with the undersigned is respectfully requested. Further, if minor amendments may be achieved by Examiner's amendment, a call to the undersigned attorney is also respectfully requested.

Respectfully submitted,



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